Atty Doc. No. HME/7477.0017

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of Stephen P. Oliver, et al	: :	Group Art Unit: 1645
Serial No. 10/691,384	:	Examiner: Devi, Sarvamangala JN
Filed: October 22, 2003	:	
For a Patent for STREPTOCOCCUS UBERIS ADHESION MOLECULE	:	

DECLARATION OF STEPHEN P. OLIVER UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. I, Stephen P. Oliver, am one of the inventors named in the present application. I am familiar with the prosecution of this application.

2. In an Office Action dated March 8, 2007, the Examiner rejected claims 1-5 and 11-14 of this application under 35 U.S.C. §102(b) as being anticipated by Park et al, In: Proceedings of the 40th Annual Meeting of National Mastitis Council, National Council Incorporated, pages 247-248 (February 2001), hereinafter referred to as "the Abstract." I am a co-author of the Abstract.

3. I am testifying in this Declaration to establish that the Abstract cited by the Examiner does not provide an enabling disclosure by which a person of skill in the art would be able to make and use the claimed invention.

4. In the Abstract, the authors compared two methods for the extraction of surface proteins from *Streptococcus uberis* and for the detection of lactoferrin-binding proteins (LBP's) within the multiplicity of extracted proteins. One of the methods described in the Abstract was an adaptation of general procedures used for detection of surface proteins in *Streptococcus* species reported by Galan & Timoney (1985) and Boschwit et al. (1991). This method is based on enzymatic degradation of the Gram-positive cell wall followed by sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE), transfer to nitrocellulose membrane, and detection of protein(s) using specific antibodies in a Western blot protocol. The second method is based on use of SDS and it was adapted from the SDS-PAGE sample buffer formulation described by Laemmli (1970). Proteins that were transferred onto nitrocellulose were then detected through use of specific antibodies that interacted specifically with the selected protein. In the methods described in the Abstract, a modification of the classical Western blot protocol was used in that lactoferrin (LF) and not specific antibody was used to detect bacterial proteins that bind LF. In both methods, the bacterial protein-LF complex was then detected by using antibodies produced in rabbits against LF.

5. Following the extraction of bacterial surface proteins from *S. uberis*, either with SDS or mutanolysin, the surface proteins were electrophoresed by polyacrylamide gel

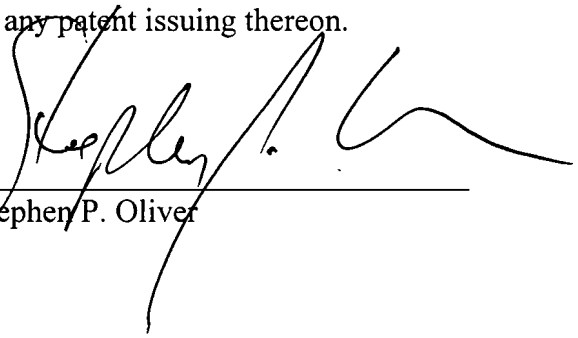
electrophoresis (PAGE). At this point, a large number of proteins of various sizes were distributed, based upon molecular weight, in bands in the polyacrylamide gel. This mixture of proteins from the gel were then transferred onto a nitrocellulose membrane. The membrane was then probed with LF and the bacterial protein - LF complexes were detected on the membrane by probing with antibodies directed against LF.

6. The methods described in the Abstract resulted in a detection of lactoferrin binding protein (LBP), following extraction of bacterial surface proteins from the total protein pool in the bacterial cell wall. The methods described in the Abstract do not result in purification of LBP, but only in a visible detection that LBP was within the extracted pool of bacterial surface proteins, and more precisely was within the region of the gel (110 to 112 kDa) that included this protein plus other bacterial surface proteins of comparable size. That the LBP was not purified, but merely detected in a crude extract that contained a pool of surface proteins, is emphasized in the last line of the Abstract, which states that the extraction method of the Abstract is suitable to extract LBP for purification.

7. Following the procedure described in the Abstract, which is the same as that described in the present patent application in Example 4, much additional experimental work was required in order to obtain purified LBP, referred to in the application as *Streptococcus uberis* Adhesion Molecule (SUAM). Example 6 of the application describes the process that was developed that allowed the inventors to obtain purified SUAM from extracted *S. uberis* surface proteins.

8. It is my understanding that, in order to find that a claimed invention is anticipated by a cited reference, the reference must teach one skilled in the art how to make and how to use the claimed invention. My testimony herein establishes that the Abstract does not teach one skilled in the art how to make the claimed invention because the methods disclosed in the Abstract do not result in a purified protein that is SUAM. Rather, in order to obtain purified SUAM from extracted streptococcal surface proteins, which proteins may be obtained by the methods disclosed in the Abstract, a significant amount of additional experimental work was required. In the hands of the inventors, this additional experimental work resulted in the method described in Example 6 of the patent application, by which purified SUAM was obtained.

I hereby declare that all that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Stephen P. Oliver

05/23/07

Date